REMARKS

Claim 1 has been amended. Claims 19-33 have been withdrawn. Claims 34 and 35 have been added. Claims 34-35 contain no new matter. Claims 1-18 and 34-35 are pending. Claims 1-18 have been rejected.

I. Restriction Requirement

Applicant affirms that on June 14, 2006, a provisional election with traverse was made during a telephonic conversation with the Examiner. The Examiner has set forth a restriction requirement asserting that two distinct inventions exist, namely Group I for claims 1-18, drawn to a drug delivery system comprising a pad, container, and an emulsion comprising insoluble active ingredients classified in class 424, subclass 449; and Group II for claims 19-33, drawn to a drug delivery system comprising a pad, container, and a liquid composition comprising benzoyl peroxide, starch, carbomer, disodium EDTA, water, glycerin, sodium hydroxide, zinc lactate, glycolic acid, C_{12}-C_{15} alkyl benzoate, cetearyl alcohol, dimethicone, glyceryl stearate/PEG 100 stearate, steareth 2, steareth 20, and polysorbate 20 classified in class 424, subclass 499.

Applicant respectfully traverses the restriction requirement. According to MPEP §808.02, "[w]here [] the classification is the same and the field of search is the same and there is no clear indication of separate future classification and field of search, no reasons exist for dividing among independent or related inventions." The Examiner has indicated that the claims of Group I and Group II both fall under the same class and subclass, 424 and 499, respectfully. Further, the claims of Group I and Group II all pertain to the same invention, a drug delivery system comprising a pad, a container, and a liquid composition with a described viscosity. A search of the prior art for the claims of Group I would necessarily overlap with the search for the claims of Group II. As such, Applicant respectfully requests the restriction requirement be withdrawn.

II. Claim Rejections.

In the Office Action mailed June 22, 2006, the Examiner rejected the claims on the following grounds: 1) Claims 1-18 were rejected under 35 U.S.C. §112 as failing to comply with the written description requirement; 2) Claims 1-18 were rejected under 35 U.S.C. §112 for lack

of enablement for the use of all insoluble drugs in an emulsion; 3) Claims 1-18 were rejected under 35 U.S.C. §112 as indefinite in light of the use of certain terms in the claims; 4) Claims 1, 2, 6, 7, and 14-18 were rejected under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 5,562,642; 5) Claims 1, 2, 6, 7, 14, and 16-18 were rejected under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 6,183,766; 6) Claims 3-5 and 8-13 were rejected under 35 U.S.C. §103 as obvious in light of U.S. Patent. No. 5,562,642; 7) Claims 3-5 and 8-13 were rejected under 35 U.S.C. §103 as obvious in light of U.S. Patent No. 6,183,766; 8) Claims 4 and 5 were rejected under 35 U.S.C. §103 as obvious in light of U.S. Patent Nos. 5,562,643 and 6,183,766; 9) Claim 15 was rejected under 35 U.S.C. §103 as obvious in light of U.S. Patent Nos. 6,183,766 and 5,562,642; 10) Claims 1-18 were rejected under 35 U.S.C. §103 as obvious in light of U.S. Patent Nos. 6,784,145 and 5,562,642; 11) Claims 4, 5, and 8-12 were rejected under 35 U.S.C. §103 as obvious in light of U.S. Patent Nos. 5,562,642 and 6,784,145; 12) Claims 8-12 were rejected under 35 U.S.C. §103 as obvious in light of U.S. Patent Nos. 6,183,766 and 6,784,145; 13) Claims 1018 were rejected under 35 U.S.C. §103 as obvious in light of U.S. Patent Nos. 6,338,855 and 5,562,642; and 14) Claims 4, 5, and 8-12 were rejected under 35 U.S.C. §103 as obvious in light of U.S. Patent Nos. 6,338,855; 5,562,642; and 6,784,145. Applicant respectfully traverses these rejections and requests reconsideration for the reasons stated below.

III. The Rejections under 35 U.S.C. §112.

Written Description

The Examiner asserts that no definition is given to the medicines and active ingredients listed in the specification at paragraph 12 and that the specification provides no guidance to one of ordinary skill in the art to the insoluble active ingredients. It is the Applicant's position that the medicines and active ingredients are described in the specification in such as way as to reasonably convey to one of ordinary skill in the art at the time the application was filed, that the Applicant had possession of the claimed invention and therefore satisfy the requirements of 35 U.S.C. §112.

35 U.S.C. §112, paragraph 1, states "[t]he specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with

which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention."

The Examiner has rejected claims 1-18 under the written description requirement. However, the Examiner's rejection cannot apply to claims 3 and 4 because they specifically set forth the active ingredient benzoyl peroxide and the particle size of the BPO. In the instant Office Action, the Examiner concedes that the specification defines the insoluble drug BPO. *See* Office Action mailed June 22, 2006, p. 5. Therefore, the rejection must be withdrawn, at minimum for these claims.

One of ordinary skill in the art would understand the medications listed in the specification because they are all art recognized terms. For example, the World Health Organization (WHO) provides extensive information on traditional medicine, as well as herbal medicines. Specifically, the WHO defines "traditional medicine" as "an ancient medical practice that existed in human societies before the application of modern science to health." *See* Exhibit 1. The WHO defines herbal medicine to include "herbs, herbal materials, herbal preparations and finished herbal products that contain as active ingredients parts of plants, or other plant materials, or combinations." *See* Exhibit 2. Examples of traditional and herbal medicines include turmeric and piper nigrum. *See* Exhibit 3, p. 9 and 17. It is apparent that one of ordinary skill in the art would understand the meaning of traditional and herbal medicine, especially in light of the fact that they have been around far longer than the filing date of the present application.

Additionally, the terms prodrug, cosmeceutical, and active cosmetic ingredients are also well-known in the art. For example, prodrugs are defined as precursors of drugs that "must undergo a chemical conversion by a metabolic process before becoming active," like 5-aminolaevulinic acid and bis(o-carboxyphenyl ethyl ester) nonanedioate. *See* Exhibit 4 and 5. Further, the term cosmeceutical was "created in the 1990s from cosm(etic) + (pharma)ceutic" and is defined as "a cosmetic product claimed to have medicinal or drug-like benefits." *See* Exhibit 6. The term is well-known in the pharmaceutical business. *Id.* Further, a search of the USPTO patent database reveals numerous patents using the term "cosmeceutical." For example, U.S. Patent No. 6,984,391 is entitled "Composition and Methods for the Delivery of Skin

Cosmeceuticals." For additional patents highlighting this well-known term of art, *see* Exhibit 7. Applicant has also attached additional references setting forth examples of insoluble active ingredients illustrating that the terms are art recognized. *See* Exhibit 8.

Therefore, having produced actual evidence in response to the Examiner's mere assertions, the rejection must be withdrawn absent evidence in the form of documents or declarations by the Examiner.

Enablement

The Examiner rejects claims 1-18 because "the specification, while being enabling for using BPO, does not reasonably provide enablement for the use of all insoluble drugs in an emulsion." Office Action, p. 6. Further, the Examiner asserts that the "specification provides no guidance, in the way [of] written description, on all insoluble prodrugs, herbal medicines, traditional medicines, and active cosmetic ingredients" and cites *In re Dreshfield* and an article by Samuel S. Levin to support her premise. However, not only are the insoluble drugs enabled by the specification, but the Examiner's cited references fail to support her premise.

First, the Examiner has rejected claim 3, which depends from claim 1 and states "[t]he system of claim 1 wherein the active ingredient comprises benzoyl peroxide." The Examiner has also rejected claim 4, which depends from claim 3 and states, "[t]he system of claim 3 wherein the benzoyl peroxide comprises particles of less than about 50 microns." Thus, claims 3 and 4 should not be rejected for lack of enablement because the Examiner has set conceded that the specification is enabled for BPO. As such, Applicants respectfully request that, at a minimum, this rejection be withdrawn as to claims 3 and 4.

Second, as discussed at page 8 *supra* the terms used in the specification and in the instant claims for the types of insoluble "dermatologically active ingredients," including prodrug, traditional medicine, herbal medicine, cosmeceuticals, and cutaneously active cosmetic ingredients are all art recognized terms. Further, the claims require the insoluble active ingredient to be one recognized as a "dermatologically active ingredient," not "all insoluble drugs" as asserted by the Examiner. One of ordinary skill in the art armed with the instant specification would understand what is meant by the art recognized terms and understand the

scope of the pending claims. As should be clear from the discussion at page 8 (and the evidence cited there) these compounds and their properties, including solubility, are well-known to those skilled in the art.

Third, the case of *In re Dreshfield* can be distinguished from the case at hand. In *Dreshfield*, the court cites *In re Steebock* for the premise that "[i]t is well settled that in cases involving chemicals and chemical compounds which differ radically in their properties it must appear in an applicant's specification either by the enumeration of a sufficient number of the members of a group or by other appropriate language, that the chemicals or chemical combinations included in the claims are capable of accomplishing the desired result." *In re Dreshfield*, 110 F.2d 235, 240 (Fed. Cir. 1940), quoting *In re Steebock*, 83 F.2d 912. In *Dreshfield* the claims included an antioxidant element and it was determined that "the effectiveness of any specific compound as an antioxidant could be determined only by experiment." *Id.* at 238. Thus, the claim breadth was not enabled because it was unknown whether all antioxidants would have the same catalytic action. In contrast, the present invention does not pertain to uncertain properties such as its ability to act as an antioxidant, but rather to solubility which is well-documented in the art. Thus, *In re Dreshfield* is not applicable to the present situation.

The Examiner also cites a reference by Samuel S. Levin pertaining to broad disclosures in chemical cases. Samuel L. Levin, "Broader Than the Disclosure in Chemical Cases," 31 J. Pat. & Trademark Off. Soc'y 5 (1949). This article actually supports Applicant's enablement argument. Levin cites a CCPA holding that "where no chemical reaction between the materials used is involved and the application expressly states that materials other than those specifically disclosed may be substituted, and the Examiner not only does not question that statement but suggests at least one class of other materials that could be used, held it was clearly improper to require that the claims be limited to the materials expressly disclosed." Samuel A. Levin quoting *In re Hunter*, 610 O. G. 766. The present application is concerned with the physical characteristics of the insolubility of a dermatologically active ingredient. No chemical reaction is involved. The reference also states, "it would appear that it is necessary that the disclosure show that there is a general quality common to the class being claimed and additionally, it should be borne in mind that every species under the genus must be operative." Levin, 31 J. Pat. &

Trademark Off. Soc'y 5, 13. The general quality common to the class of active ingredients is their insolubility and use in dermatology; all of which are known in the art. Thus, the instant specification provides a more than adequate enabling disclosure for the types of insoluble dermatologically active ingredients known in the art.

Indefiniteness

The Examiner asserts that claims 1-18 are indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Specifically, the Examiner asserts that (1) it is unclear whether the term "insoluble drugs" refers to it being water insoluble, alcohol insoluble, fat insoluble, etc; (2) with regard to claim 3, there is no definition regarding BPO particles with respect to the phrase "benzoyl peroxide comprises particles of less than---" because the specification refers to the droplet size of the discontinuous phase of the emulsion in the continuous phase and not the particle size of the BPO; and (3) with regard to claim 17, the specification does not define the expressions "prodrugs," "herbal medicines," "traditional medicines," and "active cosmetic ingredient."

Applicant respectfully traverses. The test for definiteness under 35 U.S.C. 112, second paragraph, is whether "those skilled in the art would understand what is claimed when the claim is read in light of the specification." *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576, (Fed. Cir. 1986). If one skilled in the art is able to ascertain the meaning of the terms in light of the specification, 35 U.S.C. 112, second paragraph, is satisfied. *Id*; *See also* MPEP §2173.02.

With respect to the Examiner's first rejection, the term "insoluble drugs" is not indefinite, but rather is set forth in the specification and claims with clarity. The specification states "[t]he dermatologically active ingredients in the invention can be any particulate or insoluble drugs including but not limited to drugs, prodrugs, cosmeceuticals, herbal medicines, traditional medicines, and active cosmetic ingredients, that are suitable for topical human use and are suspended and/or dispersed in a vehicle. Insoluble in this specification means insoluble or weakly or minimally soluble. Insoluble dermatologically active ingredients are often particulates." Specification, paragraph 12. Further, the specification states, "[t]he dermatologically active ingredient may be any drug effective in dermatological prevention or

treatment, which is insoluble in the composition and is a particulate." The claims also set forth that the active ingredients have the characteristics of being insoluble and used in dermatology, which particularly points out and distinctly claims the invention to include those dermatologically active ingredients set forth in the specification and those known to one of ordinary skill in the art. Thus, the term "insoluble drug" is definite as set forth in the claims and supported throughout the specification.

It should also be pointed out that the term "insoluble" is used in the context of dermatologically active ingredients, all of which are known to one of skill in the art, as is their solubility.

With respect to the Examiner's rejection based on the particle size of the BPO, again Applicant respectfully traverses.[1] The claims on their face refer to the particle sizes of the dermatologically active ingredient and specifically, BPO. Recourse to the specification shows that the reference to particle sizes pertains to the dermatologically active ingredients and specifically, BPO. The specification specifically states that "the dermatologically active ingredient may be any drug effective in dermatological prevention or treatment, which is insoluble in the composition and is a particulate." Specification, paragraph 15. Further, the specification discusses the particulate having various particle sizes. For example, the specification states "[t]he particle size may preferably be up to about 300 microns, more preferably about 10-150 microns. For BPO, the most preferable particle size is less than about 50 microns." Specification, paragraph 13; see also paragraph 23. Additionally, the specification states, "[i]n one embodiment, the particle size of the dermatologically active ingredient may be reduced by milling the dermatologically active ingredient..." Specification, paragraph 26. Thus, the specification clearly sets forth that the particle size element in the currently pending claims refers to the dermatologically active ingredient, and specifically BPO.

The claims as presented were completely clear on this point. However, they are amended by this submission to make it even more difficult to misconstrue them as the Examiner has done.

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1 The Examiner mistakenly refers to claim 3, when quoting from claim 4.

With respect to the Examiner's rejection based upon the expression of specific types of insoluble dermatologically active ingredients, Applicant respectfully traverses. As discussed above at page 8, the various types of insoluble dermatologically active ingredients listed in the specification and claims are all art recognized terms. As such the claims are not indefinite because they particularly point out and distinctly claim the present invention. One of ordinary skill in the art would understand the metes and bounds of the claims based upon the types of active ingredients listed and their required characteristics, in particular being used in dermatology and being insoluble.

IV. Rejections Under §102.

The Examiner has advanced two rejections under 35 U.S.C. §102(b). The Applicant believes that neither rejection can be properly maintained.

a) Rejection of Claims 1, 2, 6, 7, and 14-18

Claims 1, 2, 6, 7, and 14-18 have been rejected under 35 U.S.C. §102(b) as anticipated by U.S. 5,562,642 (the '642 Patent).

Applicant respectfully traverses and requests withdrawal of this rejection because the '642 Patent fails to teach each and every element of the claimed invention. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987). As previously point out, the viscosity limitation set forth in the claims is not taught in the '642 Patent or any of the art of record. The Examiner merely states "that viscosity is inherent to a specific composition." *See* Office Action, paragraph 28. According to MPEP §707.07, an examiner's action is required to be complete as to all matters and must provide clear explanations of all actions taken by the examiner during prosecution of an application. MPEP §707.07(f). Further the MPEP states, "[w]here the applicant traverses any rejection, the examiner should, if he or she repeats the rejection, take note of the applicant's argument and answer the substance of it." The Examiner has failed to address the substance of Applicant's arguments.

Applicant clearly pointed out in its previous response that the '642 Patent and all of the art of record fails to teach the viscosity claim limitation. *See* response filed June 5, 2006, p. 11. The Applicant has also shown how the problems of the prior art were solved by controlling the

viscosity of the fluid that is to be applied to the pad. However, the Examiner has not addressed Applicant's arguments or shown how the "viscosity is inherent to a specific composition" even though the Applicant has pointed out the lack of such disclosure in the '642 Patent, and the significance of the viscosity claim limitation. The viscosity of the claimed invention must be low enough to allow the fluid to penetrate the pad and to adhere to the pad in preference to the walls of the container, yet the viscosity must be high enough to prevent the liquid from draining off the pad (which can sometimes leave the insoluble particles behind on the pad). It has also been found that keeping the particle size of the insoluble material below a certain size also assists in solving these problems, especially the problem of the pad filtering out the particulates from the composition before it is deposited on the skin. These features are specifically set forth in the pending claims.

It should also be pointed out that the Examiner has previously conceded and reiterates in the present Office Action that the '642 Patent does not disclose controlling either viscosity or particle size, and states that claims that recite these limitations are not subject to the rejections. *See* Office Action mailed June 22, 2006, paragraph 19 and Office Action mailed February 8, 2006. Since, the '642 Patent fails to teach the claimed viscosity of the composition it fails to teach each and every claim element as required under 35 U.S.C. §102. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987).

The Examiner never addressed Applicant's argument that the only art of record to mention viscosity (i.e. the '237 Patent) is above the claimed range. Further, the Examiner has not provided any prior art teaching the claimed viscosity nor has she provided a declaration setting forth the facts within her personal knowledge that the claimed viscosity is expected as previously requested by the Applicant pursuant to 37 C.F.R. §1.104(d)(2). Since the prior art fails to teach the claimed viscosity not all of the claim elements are taught by the '642 Patent and as such, the Applicant respectfully requests this rejection be withdrawn.

b) Rejection of Claims 1, 2, 6, 7, 14 and 16-18

Claims 1, 2, 6, 7, 14, and 16-18 have been rejected under 35 U.S.C. §102(b) as anticipated by U.S. 6,183,766 (the '766 Patent).

Again, Applicant respectfully traverses and requests withdrawal of this rejection because the '766 Patent fails to teach each and every element of the claimed invention. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987). Again, the Examiner merely states that "[v]iscosity is inherent to a specific composition" without addressing the Applicant's previous arguments filed on June 5, 2006 at pages 16 and 17, and/or setting forth support for such a statement. The '766 Patent fails to teach the viscosity element. The '766 Patent only teaches viscosity with respect to specific ingredients of a composition, for example silicones and polyglycerylmethacrylate lubricants, but fails to teach the viscosity of the final composition. *See* '766 Patent, Col. 2, lines 1-6 and Col. 11, lines 56-62.

Additionally, the Examiner cites a portion of the '766 Patent showing preferred droplet sizes of the emulsion. However, there are no claims pertaining to the droplet size of the emulsion. Rather, the claims of the present invention pertain to the particle size of the insoluble dermatologically active ingredient. For example, claims 4 and 5 discuss the particle size of BPO and the active ingredient, respectively. *See supra*, p. 13. The claims as presented were completely clear on this point. However, they are amended by this submission to make it even more difficult to misconstrue them as the Examiner has done.

It should also be pointed out that the Examiner does not cite to the '766 Patent for teaching the claimed viscosity, but rather merely states that "viscosity is inherent to a specific composition." Thus, the Examiner concedes that the viscosity claim element is not taught by the '766 Patent.

Therefore, based upon the lack of teaching and the arguments set forth above, Applicant respectfully requests the rejection be withdrawn.

V. Rejections under 35 U.S.C. §103.

The Examiner has advanced nine rejections under 35 U.S.C. §103. The Applicant believes that none of the rejections can be properly maintained.

a) **Rejection of Claims 3-5 and 8-13.**

Claims 3-5 and 8-13 have been rejected under 35 U.S.C. §103(a) as obvious in view of the '642 Patent and the '766 Patent, independently.

With respect to both the '642 Patent and the '766 Patent, the Examiner concedes that they do not teach the BPO in an emulsion, the claimed particle size and viscosity, or the woven material. However, to support that each of these claimed elements are obvious in light of the cited patents she asserts that the claimed particle sizes, viscosities, and woven material do not impart patentability to the claims, absent evidence to the contrary. The Examiner is required to examine the claims as a whole, including each and every element discussed therein. MPEP §2143.03. According to *In re Wilson*, "[a]ll words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385 (CCPA 1970). Accordingly, all the claim elements, including the viscosity and particle sizes, must be considered.

The Examiner also merely asserts that the '642 Patent and the '766 Patent "suggest[] the use of BPO for skin application from a pad and also suggests the emulsion" and that "[i]t is expected that the viscosity of the composition disclosed by the reference[s] having the same ingredients as the claimed composition to have the same viscosity." As discussed in Applicant's previous response filed on June 5, 2006 and as discussed above at pages 14-16, the '642 Patent is silent as to the viscosity of the composition and the particle sizes of the active ingredient. Further, the '766 Patent only mentions the viscosity of some of the ingredients of the composition and not the final composition. The Examiner's "expectation" that the viscosity of the prior art would be the same as the claimed invention lacks support. The Examiner has not put forth prior art showing or a declaration attesting to the fact that the viscosity would be "expected" to be the same as requested by the Applicant's in their response filed on June 5, 2006, at page 14.

The Examiner again fails to respond to the Applicant's previously filed arguments. The Examiner's statement that the composition disclosed in the prior art has "the same ingredients as the claimed composition" is true only in that the references disclose a liquid that has insoluble particles on pad in a container. Both the '642 Patent and the '766 Patent fail to even mention the

viscosity or particle size, much less the specific ranges called for by claims 4, 5, and 8-12. Further, the art of records actually teach one of ordinary skill in the art to stay out of the claimed viscosity ranges, thereby teaching away from the present invention. If the viscosity is expected to be the same based upon the Examiner's same ingredients argument, then it follows that the only other prior art reference of record which mentions viscosity (i.e., the '237 Patent) would have the same viscosity of the claimed invention. However, the '237 Patent teaches viscosities in a preferably range of 50,000 to about 150,000 cps, which is well above the viscosity of the claimed invention. *See* the '237 Patent, Col. 13, lines 25-28 and the currently pending claims. Therefore, since both patents fail to teach the claimed invention, Applicant respectfully requests the rejection be withdrawn

b) Rejection of Claims 4 and 5

Claims 4 and 5 have been rejected under 35 U.S.C. §103(a) as obvious over the '642 Patent in view of the '766 Patent.

The '766 Patent fails to teach the specific active ingredient (e.g. BPO) particle sizes of claims 4 and 5. As discussed above at pages 12 and 13, claims 4 and 5 pertain to the particle size of BPO and the active ingredient, respectively. The '766 Patent does not teach "particle sizes of the emulsion are preferred to be between 0.2 and 200 micron." Office Action, p. 14. Rather, the '766 Patent teaches that "[t]he average droplet size of the moisturizing phase droplets, which comprise the lipophilic skin moisturizing agent, ranges from about 0.005 microns to about 1000 microns, preferably from about 0.1 to about 500 microns, and more preferably from about 0.2 to about 200 microns in diameter." *See* Col. 4, lines 24-29. Therefore, for this and other reasons, claim 4 and 5 are not obvious over the cited art of record.

c) Rejection of Claim 15

Claim 15 has been rejected under 35 U.S.C. §103(a) as obvious over the '766 Patent in view of the '642 Patent.

As discussed above at pages 13 to 15, both the '766 Patent and the '642 Patent fail to teach each and every element of the claimed invention, in particular the viscosity of the composition. As previously mentioned, the '766 Patent only teaches viscosity with respect to

specific ingredients of a composition, for example silicones and polyglycerylmethacrylate lubricants, and fails to teach the viscosity of the final composition. *See* '766 Patent, Col. 2, lines 1-6 and Col. 11, lines 56-62.

Therefore, the '766 Patent and the '642 Patent even if properly combined fail to teach every claim element and fail to render the invention obvious.

d) Rejection of Claims 1-18

Claims 1-18 have been rejected under 35 U.S.C. §103(a) as being obvious over U.S. 6,784,145 (the '145 Patent) in view of the '642 Patent.

The Examiner asserts that the '145 Patent teaches, among other things, the viscosity and particle sizes of the claimed invention. However, a review of the cited references reveals that the references fail to teach viscosity of all the claims, especially the ones with numerical values, as well as the claimed particles sizes of the insoluble dermatologically active ingredient.

The Examiner notes that the '145 Patent teaches a composition that has a viscosity below 150 mPa.s in order to be suitable to impregnate the substrate. This viscosity is well below the range of the claimed invention. A conversion from mPa.s to cps must be done in order to get a perspective on how low 150 mPa.s is compared to the present invention. The following conversions are provided below:

1 mPa.s = 1 cps

150 mPa.s = 150 cps

See Exhibit 9 for a viscosity conversion chart.

Thus, the '145 Patent teaches a composition with a viscosity below 150 cps at room temperature (25° C) with a Rheomat RM 180 machine, using a No. 1 spindle. At a viscosity below 150 cps, this reference fails miserably to teach the viscosity of the claimed invention. For example, claim 8 teaches a viscosity range of about 500 to about 9000 cps using a Brookfield viscometer LVT model at a temperature of about 27° C for 60 seconds and a spindle set for 30 rpm. The viscosity taught in the '145 Patent is significantly below that of the claimed invention.

Thus, '145 Patent actually teaches away from the viscosity of the claimed invention because a viscosity of 150 cps is substantially below the claimed viscosities and fails to solve the retention and application problems in the art.

Again, it is important to point out that the only other prior art of record that mentions viscosity is the '237 Patent and as Applicant has previously pointed out at pages 16 and 17, the '237 Patent teaches viscosities in a preferably range of 50,000 to about 150,000 cps, which is significantly above the viscosity of the claimed invention.

The '145 Patent also fails to teach the particle size of the insoluble dermatologically active ingredient as claimed. *See supra*, page 15. The Examiner cites to a part of the '145 Patent that discusses the globule size of the emulsion, which is not the particle size of the insoluble dermatologically active ingredient. The '145 Patent does not disclose the particle size for insoluble dermatologically active ingredients, including BPO.

Therefore, since the '145 Patent and the '642 Patent fail to teach the viscosity and particle size claim elements, the claims are not obvious in view of the cited art.

e) Rejection of Claims 4, 5, and 8-12

Claims 4, 5, and 8-12 have been rejected under 35 U.S.C. §103(a) as obvious over the '642 Patent in view of the '145 Patent.

Again, as discussed above at pages 19 and 20, the '642 Patent and the '145 Patent fail to teach the claimed particle sizes and the claimed viscosity. It is inconsequential whether the '642 Patent teaches droplet sizes of the disclosed emulsion between 50-1000 microns because the claims do not (and never did) have any limitations pertaining to the droplet size of the emulsion. Rather, the currently pending claims pertain to the particle size of the insoluble dermatologically active ingredient. For example, claim 4 clearly refers to the particle size of BPO (and always did). Further, '145 Patent teaches away from the viscosity of the claimed invention because as calculated above at page 18, a viscosity of 150 cps is significantly below the claimed viscosities. Therefore, the claims of the present invention are not rendered obvious in view of the cited art.

f) Rejection of Claims 8-12

Claims 8-12 are rejected under 35 U.S.C. §103(a) as being obvious over the '766 Patent in view of the '145 Patent.

As discussed above at pages 16 to 19, the '766 Patent and the '145 Patent fail to teach the claimed particle sizes and claimed viscosity. Further, as pointed out above, the '145 Patent teaches a viscosity so low that the reference actually teaches way from the present invention. Therefore, the claims of the present invention are not rendered obvious in view of the cited art.

g) Rejection of Claims 1-18

Claims 1-18 are rejected under 35 U.S.C. §103(a) as being obvious over U.S. 6,338,855 (the '855 Patent) in view of the '642 Patent.

The Examiner asserts that the '855 Patent teaches all of the claim elements except the article in a container, the particle sizes, and the viscosity of the composition, which are found in the '642 Patent. Additionally, the Examiner again asserts that the claimed particle sizes and viscosity do not impart patentability to the claims "because the art recognized the desire to have viscosity of the impregnated composition enough to retain the composition in the pad, absent evidence to the contrary." As previously discussed on page 14, the Applicant has pointed out the problems associated with insoluble active ingredients and their delivery with applicator pads. For example, the pads often act to filter out the particles from the liquid and retain the particles on the pad matrix. For insoluble, particular therapeutic agents, such as BPO, this can result in the retention of so much of the therapeutic agent in the pad or cloth that a sub-optimal or even sub-therapeutic amount of the agent is delivered to the skin. Another problem addressed by this invention has to do with the difficulty in controlling the "release" of the fluid from the pad. One must firmly retain the particle-containing fluid on the cloth or pad applicator prior to use, but readily release the particle-containing fluid from the applicator pad or cloth when actually used.

The '855 Patent pertains to a substantially dry, disposable, personal cleansing article useful for both cleansing the skin or hair and delivering skin care actives to the skin or hair. *See* Abstract. The cleansing article works by application of water to the article by the user and working up a lather prior to application. *See* Abstract. This is in contrast to the present

invention. The present invention has a pad that holds a liquid composition such that the insoluble dermatologically active ingredient is absorbed onto the pad and retained on the pad. The claimed drug delivery system comprises a pad with a liquid composition that is ready for application upon removal from the container. Additionally, as the Examiner has acquiesced, the '855 Patent fails to teach a container, the particle sizes, and the viscosity of the composition. Therefore, the '855 Patent fails to teach the claimed invention because it requires the addition of water to the cleansing article prior to application and does not teach the claim elements of the container, the particle sizes, and the viscosity of the composition.

The '642 Patent does not make up for the deficiencies of the '855 Patent as discussed above and pointed out by the Examiner. As discussed on pages 14 and 15, the '642 Patent does not teach the claimed viscosity or the particle sizes of the dermatologically active ingredient. Therefore, since each and every claim element is not taught by the cited references, the presently claimed invention is not obvious over the references.

h) Rejection of Claims 4, 5, 8-12

Claims 4, 5, 8-12 are rejected under 35 U.S.C. §103(a) as obvious over the '855 Patent in view of the '642 Patent and further in view of the '145 Patent.

Again, as discussed above at pages 19 and 20, the '642 Patent and the '145 Patent fail to teach the claimed particle sizes and the claimed viscosity. Further, the particle size element refers to the size of the insoluble dermatologically active ingredient; for example, claim 4 clearly refers to the particle size of BPO (and always did). Contrary to the Examiner's assertions, the '145 Patent does not teach the same ranges of particles sizes or the viscosity of the composition. Further, one cannot correlate that the disclosed emulsion particle sizes and significantly low viscosity teach the claimed invention because they are suitable for impregnating the composition into a substrate. Once again, the problems overcome by the present invention are not addressed in the prior art references, in particular substantially uniform absorption onto the pad and substantially uniform delivery of the dermatologically active ingredient from the pad to the site of application. Further, one of ordinary skill in the art armed with the prior art of record would not be able to or motivated to make the present invention because the teachings are so lacking. Therefore, the claims of the present invention are not rendered obvious in view of the cited art.

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CONCLUSION

In view of the foregoing remarks, Applicant respectfully requests consideration and allowance of the pending claims. Finally, Applicant respectfully submits a request for a personal interview with the Examiner, in order to further resolve any outstanding issues.

Authorization of Deposit Account

The Commissioner is hereby authorized to charge any fees which may be required during the entire pendency of this application, or credit any overpayment, to Deposit Account No. 18-0586. This authorization also hereby includes a request for any extensions of time of the appropriate length required upon the filing of any reply during the entire pendency of this application.

I hereby certify that this paper and the papers referred to herein as being transmitted, submitted, or enclosed herewith in connection with U.S. Serial No. 10/613,698 is/are being facsimile transmitted to the United States Patent and Trademark Office fax number 571-273-8300 on the date shown below.

Tamara Yorita

Date of Facsimile Transmission: October 4, 2006.

Respectfully submitted,
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